

**Amendments to the Claims:**

This listing of claims will replace all prior versions, and listings, of claims in the application:

**Listing of Claims:**

1-155 (cancelled).

156 (currently amended). A method for safely immunizing ~~humans~~ a human with one or more doses of one or more immunogens which induce protective immunity to one or more infectious diseases when administered according to one or more immunization schedules, said method comprising

(I) ~~evaluating the~~ considering the association between said immunization schedule and one or more chronic immune mediated disorders by a) ~~comparing~~ considering the incidence, prevalence or frequency of a chronic immune mediated disorder in a first group comprising humans where the majority receive an immunization schedule comprising said one or more immunogens relative to that in at least one other ~~a control~~ group comprising humans where the majority receive a different immunization schedule, or b) ~~comparing~~ considering the risk of said chronic immune mediated disorder associated with said ~~between two or more~~ immunization schedules relative to at least one other immunization schedule of said one or more immunogens ~~where the comparisons each comprise a time span of at least one year after the administration of said one or more immunogens,~~

(II) ~~determining, at least partially on the basis of said evaluation, one or more methods of immunization to allow safe immunization with said one or more immunogens~~ screening one or more potential recipients and identifying at least one human subject who would be expected to be immunized safely with said one or more immunogens according to said immunization schedule reflective of the analysis from (I), and

(III) immunizing ~~a~~ said human against said one or more infectious diseases, ~~with one or more immunogens~~ by a safe immunization method identified in ~~(II)~~ (I).

157-191 (cancelled).

192 (new). The method of claim 156 in which the incidence, prevalence or frequency of at least one chronic immune-mediated disorder is considered.

193 (new). The method of claim 156 where data on at least two immunization schedules is derived from groups of humans who had been randomized to receive the schedules.

194 (new). The method of claim 156 where said human is immunized in III according to a schedule which is associated with a lower incidence, prevalence, frequency or risk compared to another schedule.

195 (new). The method of claim 156 wherein one schedule provides at least one dose of at least one immunogen at a later or earlier time from birth than the corresponding dose of the same immunogen is provided by another schedule.

196 (new). The method of claim 156 wherein said at least one immunogen being considered for an association is first administered in at least one schedule starting after 41 days after birth but before 180 days after birth.

197 (new). The method of claim 156 where said considering further comprises consideration for at least one possible confounding variable selected from the group consisting of breast feeding, receiving antibiotics, the maternal age, family history of a chronic immune mediated disorder, maternal infections while the human was in utero, infections during the first 12 months of life, and size of the human at birth, gestational age of the human at birth, race, date of birth.

198 (new). The method according to claim 156 where at least one immunogen being considered for an association is one other than a measles, mumps, rubella, BCG, smallpox, or pertussis immunogen.

199 (new). The method of claim 156 wherein data pertaining to at least one immunization schedule is from a clinical trial of a vaccine to test a vaccine for safety or efficacy.

200 (new). The method of claim 156 wherein at least one

said chronic immune mediated disorder comprises diabetes mellitus.

201 (new). The method of claim 156 where said considering further comprises consideration for at least one possible confounding variable selected from the group consisting of breast feeding, receiving antibiotics, the maternal age, family history of a chronic immune mediated disorder, maternal infections while the human was in utero, infections during the first 12 months of life, and size of the human at birth, gestational age of the human at birth, race, date of birth.

202 (new). The method of claim 192 where said considering further comprises consideration for at least one possible confounding variable selected from the group consisting of breast feeding, receiving antibiotics, the maternal age, family history of a chronic immune mediated disorder, maternal infections while the human was in utero, infections during the first 12 months of life, and size of the human at birth, gestational age of the human at birth, race, date of birth.

203 (new). The method of claim 193 where said considering further comprises consideration for at least one possible confounding variable selected from the group consisting of breast feeding, receiving antibiotics, the maternal age, family history of a chronic immune mediated disorder, maternal infections while the human was in utero, infections during the first 12 months of life, and size of the human at birth, gestational age of the human at birth, race, date of birth.

204 (new). The method of claim 194 where said considering further comprises consideration for at least one possible confounding variable selected from the group consisting of breast feeding, receiving antibiotics, the maternal age, family history of a chronic immune mediated disorder, maternal infections while the human was in utero, infections during the first 12 months of life, and size of the human at birth, gestational age of the human at birth, race, date of birth.

205 (new). The method of claim 195 where said considering

further comprises consideration for at least one possible confounding variable selected from the group consisting of breast feeding, receiving antibiotics, the maternal age, family history of a chronic immune mediated disorder, maternal infections while the human was in utero, infections during the first 12 months of life, and size of the human at birth, gestational age of the human at birth, race, date of birth.

206 (new). The method of claim 196 where said considering further comprises consideration for at least one possible confounding variable selected from the group consisting of breast feeding, receiving antibiotics, the maternal age, family history of a chronic immune mediated disorder, maternal infections while the human was in utero, infections during the first 12 months of life, and size of the human at birth, gestational age of the human at birth, race, date of birth.

207 (new). The method of claim 198 where said considering further comprises consideration for at least one possible confounding variable selected from the group consisting of breast feeding, receiving antibiotics, the maternal age, family history of a chronic immune mediated disorder, maternal infections while the human was in utero, infections during the first 12 months of life, and size of the human at birth, gestational age of the human at birth, race, date of birth.

208 (new). The method of claim 199 where said considering further comprises consideration for at least one possible confounding variable selected from the group consisting of breast feeding, receiving antibiotics, the maternal age, family history of a chronic immune mediated disorder, maternal infections while the human was in utero, infections during the first 12 months of life, and size of the human at birth, gestational age of the human at birth, race, date of birth.

209 (new). The method of claim 200 where said considering further comprises consideration for at least one possible confounding variable selected from the group consisting of breast feeding, receiving antibiotics, the maternal age, family history

of a chronic immune mediated disorder, maternal infections while the human was in utero, infections during the first 12 months of life, and size of the human at birth, gestational age of the human at birth, race, date of birth.

210 (new). The method of claim 156 where said considering further comprises consideration for the possible confounding effect from exposure to one or more vaccine immunogens other than said one or more immunogens being considered for an association.

211 (new). The method of claim 192 where said considering further comprises consideration for the possible confounding effect from exposure to one or more vaccine immunogens other than said one or more immunogens being considered for an association.

212 (new). The method of claim 193 where said considering further comprises consideration for the possible confounding effect from exposure to one or more vaccine immunogens other than said one or more immunogens being considered for an association.

213 (new). The method of claim 194 where said considering further comprises consideration for the possible confounding effect from exposure to one or more vaccine immunogens other than said one or more immunogens being considered for an association.

214 (new). The method of claim 195 where said considering further comprises consideration for the possible confounding effect from exposure to one or more vaccine immunogens other than said one or more immunogens being considered for an association.

215 (new). The method of claim 196 where said considering further comprises consideration for the possible confounding effect from exposure to one or more vaccine immunogens other than said one or more immunogens being considered for an association.

216 (new). The method of claim 197 where said considering

further comprises consideration for the possible confounding effect from exposure to one or more vaccine immunogens other than said one or more immunogens being considered for an association.

217 (new). The method of claim 198 where said considering further comprises consideration for the possible confounding effect from exposure to one or more vaccine immunogens other than said one or more immunogens being considered for an association.

218 (new). The method of claim 199 where said considering further comprises consideration for the possible confounding effect from exposure to one or more vaccine immunogens other than said one or more immunogens being considered for an association.

219 (new). The method of claim 200 where said considering further comprises consideration for the possible confounding effect from exposure to one or more vaccine immunogens other than said one or more immunogens being considered for an association.

220 (new). The method of claim 156 wherein one or more humans are excluded from receiving said one or more immunogens if: i) said humans have substantial immunologic protection against the infectious disease which said immunization schedule protects against, or ii) said humans have an hyperactive immune response or iii) said humans have a surrogate marker of an hyperactive immune response.

221 (new). The method of claim 192 wherein one or more humans are excluded from receiving said one or more immunogens if: i) said humans have substantial immunologic protection against the infectious disease which said immunization schedule protects against, or ii) said humans have an hyperactive immune response or iii) said humans have a surrogate marker of an hyperactive immune response.

222 (new). The method of claim 193 wherein one or more humans are excluded from receiving said one or more immunogens

if: i) said humans have substantial immunologic protection against the infectious disease which said immunization schedule protects against, or ii) said humans have an hyperactive immune response or iii) said humans have a surrogate marker of an hyperactive immune response.

223 (new). The method of claim 194 wherein one or more humans are excluded from receiving said one or more immunogens if: i) said humans have substantial immunologic protection against the infectious disease which said immunization schedule protects against, or ii) said humans have an hyperactive immune response or iii) said humans have a surrogate marker of an hyperactive immune response.

224 (new). The method of claim 195 wherein one or more humans are excluded from receiving said one or more immunogens if: i) said humans have substantial immunologic protection against the infectious disease which said immunization schedule protects against, or ii) said humans have an hyperactive immune response or iii) said humans have a surrogate marker of an hyperactive immune response.

225 (new). The method of claim 196 wherein one or more humans are excluded from receiving said one or more immunogens if: i) said humans have substantial immunologic protection against the infectious disease which said immunization schedule protects against, or ii) said humans have an hyperactive immune response or iii) said humans have a surrogate marker of an hyperactive immune response.

226 (new). The method of claim 197 wherein one or more humans are excluded from receiving said one or more immunogens if: i) said humans have substantial immunologic protection against the infectious disease which said immunization schedule protects against, or ii) said humans have an hyperactive immune response or iii) said humans have a surrogate marker of an hyperactive immune response.

227 (new). The method of claim 198 wherein one or more humans are excluded from receiving said one or more immunogens

if: i) said humans have substantial immunologic protection against the infectious disease which said immunization schedule protects against, or ii) said humans have an hyperactive immune response or iii) said humans have a surrogate marker of an hyperactive immune response.

228 (new). The method of claim 199 wherein one or more humans are excluded from receiving said one or more immunogens if: i) said humans have substantial immunologic protection against the infectious disease which said immunization schedule protects against, or ii) said humans have an hyperactive immune response or iii) said humans have a surrogate marker of an hyperactive immune response.

229 (new). The method of claim 200 wherein one or more humans are excluded from receiving said one or more immunogens if: i) said humans have substantial immunologic protection against the infectious disease which said immunization schedule protects against, or ii) said humans have an hyperactive immune response or iii) said humans have a surrogate marker of an hyperactive immune response.

230 (new). The method of claim 156 wherein said at least one immunogen is given when said humans are less than 42 days old.

231 (new). The method of claim 192 wherein said at least one immunogen is given when said humans are less than 42 days old.

232 (new). The method of claim 193 wherein said at least one immunogen is given when said humans are less than 42 days old.

233 (new). The method of claim 194 wherein said at least one immunogen is given when said humans are less than 42 days old.

234 (new). The method of claim 195 wherein said at least one immunogen is given when said humans are less than 42 days old.

235 (new). The method of claim 196 wherein said at least one immunogen is given when said humans are less than 42 days old.

236 (new). The method of claim 197 wherein said at least one immunogen is given when said humans are less than 42 days old.

237 (new). The method of claim 198 wherein said at least one immunogen is given when said humans are less than 42 days old.



238 (new). The method of claim 199 wherein said at least one immunogen is given when said humans are less than 42 days old.

239 (new). The method of claim 200 wherein said at least one immunogen is given when said humans are less than 42 days old.

240 (new). The method of claim 156 wherein said at least one immunogen being considered for an association is first administered in at least one schedule starting after 41 days after birth but before 180 days after birth.

241 (new). The method of claim 192 wherein said at least one immunogen being considered for an association is first administered in at least one schedule starting after 41 days after birth but before 180 days after birth.

242 (new). The method of claim 193 wherein said at least one immunogen being considered for an association is first administered in at least one schedule starting after 41 days after birth but before 180 days after birth.

243 (new). The method of claim 194 wherein said at least one immunogen being considered for an association is first administered in at least one schedule starting after 41 days after birth but before 180 days after birth.

244 (new). The method of claim 195 wherein said at least one immunogen being considered for an association is first administered in at least one schedule starting after 41 days after birth but before 180 days after birth.

245 (new). The method of claim 197 wherein said at least one immunogen being considered for an association is first administered in at least one schedule starting after 41 days after birth but before 180 days after birth.

246 (new). The method of claim 198 wherein said at least one immunogen being considered for an association is first administered in at least one schedule starting after 41 days after birth but before 180 days after birth.

247 (new). The method of claim 199 wherein said at least one immunogen being considered for an association is first administered in at least one schedule starting after 41 days

after birth but before 180 days after birth.

248 (new). The method of claim 200 wherein said at least one immunogen being considered for an association is first administered in at least one schedule starting after 41 days after birth but before 180 days after birth.

249 (new). The method of claim 156 wherein one schedule provides at least one dose of at least one immunogen at a later or earlier time from birth than the corresponding dose of the same immunogen is provided by another schedule.

250 (new). The method of claim 192 wherein one schedule provides at least one dose of at least one immunogen at a later or earlier time from birth than the corresponding dose of the same immunogen is provided by another schedule.

251 (new). The method of claim 193 wherein one schedule provides at least one dose of at least one immunogen at a later or earlier time from birth than the corresponding dose of the same immunogen is provided by another schedule.

252 (new). The method of claim 194 wherein one schedule provides at least one dose of at least one immunogen at a later or earlier time from birth than the corresponding dose of the same immunogen is provided by another schedule.

253 (new). The method of claim 196 wherein one schedule provides at least one dose of at least one immunogen at a later or earlier time from birth than the corresponding dose of the same immunogen is provided by another schedule.

254 (new). The method of claim 197 wherein one schedule provides at least one dose of at least one immunogen at a later or earlier time from birth than the corresponding dose of the same immunogen is provided by another schedule.

255 (new). The method of claim 198 wherein one schedule provides at least one dose of at least one immunogen at a later or earlier time from birth than the corresponding dose of the same immunogen is provided by another schedule.

256 (new). The method of claim 199 wherein one schedule provides at least one dose of at least one immunogen at a later

or earlier time from birth than the corresponding dose of the same immunogen is provided by another schedule.

257 (new). The method of claim 200 wherein one schedule provides at least one dose of at least one immunogen at a later or earlier time from birth than the corresponding dose of the same immunogen is provided by another schedule.

258 (new). The method of claim 156 where at least two schedules differ by a difference in the number of doses of at least one immunogen administered.

259 (new). The method of claim 192 where at least two schedules differ by a difference in the number of doses of at least one immunogen administered.

260 (new). The method of claim 193 where at least two schedules differ by a difference in the number of doses of at least one immunogen administered.

261 (new). The method of claim 194 where at least two schedules differ by a difference in the number of doses of at least one immunogen administered.

262 (new). The method of claim 195 where at least two schedules differ by a difference in the number of doses of at least one immunogen administered.

263 (new). The method of claim 196 where at least two schedules differ by a difference in the number of doses of at least one immunogen administered.

264 (new). The method of claim 197 where at least two schedules differ by a difference in the number of doses of at least one immunogen administered.

265 (new). The method of claim 198 where at least two schedules differ by a difference in the number of doses of at least one immunogen administered.

266 (new). The method of claim 199 where at least two schedules differ by a difference in the number of doses of at least one immunogen administered.

267 (new). The method of claim 200 where at least two schedules differ by a difference in the number of doses of at

least one immunogen administered.

268 (new). The method of claim 156 wherein in said at least one immunogen being considered for an association is other than a live vaccine.

269 (new). The method of claim 192 wherein in said at least one immunogen being considered for an association is other than a live vaccine.

270 (new). The method of claim 193 wherein in said at least one immunogen being considered for an association is other than a live vaccine.

271 (new). The method of claim 194 wherein in said at least one immunogen being considered for an association is other than a live vaccine.

272 (new). The method of claim 195 wherein in said at least one immunogen being considered for an association is other than a live vaccine.

273 (new). The method of claim 196 wherein in said at least one immunogen being considered for an association is other than a live vaccine.

274 (new). The method of claim 197 wherein in said at least one immunogen being considered for an association is other than a live vaccine.

275 (new). The method of claim 198 wherein in said at least one immunogen being considered for an association is other than a live vaccine.

276 (new). The method of claim 199 wherein in said at least one immunogen being considered for an association is other than a live vaccine.

277 (new). The method of claim 200 wherein in said at least one immunogen being considered for an association is other than a live vaccine.

278 (new). The method according to claim 156 where said at least one immunogen being considered for an association is one other than a measles, mumps, rubella, BCG, or smallpox or pertussis immunogen.

279 (new). The method according to claim 192 where said at least one immunogen being considered for an association is one other than a measles, mumps, rubella, BCG, smallpox or pertussis immunogen.

280 (new). The method according to claim 193 where said at least one immunogen being considered for an association is one other than a measles, mumps, rubella, BCG, smallpox or pertussis immunogen.

281 (new). The method according to claim 194 where said at least one immunogen being considered for an association is one other than a measles, mumps, rubella, BCG, smallpox or pertussis immunogen.

282 (new). The method according to claim 195 where said at least one immunogen being considered for an association is one other than a measles, mumps, rubella, BCG, smallpox or pertussis immunogen.

283 (new). The method according to claim 196 where said at least one immunogen being considered for an association is one other than a measles, mumps, rubella, BCG, smallpox or pertussis immunogen.

284 (new). The method according to claim 197 where said at least one immunogen being considered for an association is one other than a measles, mumps, rubella, BCG, smallpox or pertussis immunogen.

285 (new). The method according to claim 199 where said at least one immunogen being considered for an association is one other than a measles, mumps, rubella, BCG, smallpox or pertussis immunogen.

286 (new). The method according to claim 200 where said at least one immunogen being considered for an association is one other than a measles, mumps, rubella, BCG, smallpox or pertussis immunogen.

287 (new). The method of claim 156 where said at least one immunogen being considered for an association comprises at least one of the following, BCG, measles, mumps, rubella, diphtheria,

pertussis, Hemophilus influenza, tetanus, hepatitis B, polio, anthrax, plague, encephalitis, meningococcal, meningitis, pneumococcus, typhus, typhoid fever, streptococcus, staphylococcus, neisseria, lyme, cytomegalovirus (CMV), respiratory syncytial virus, Epstein Barr virus, herpes, influenza, parainfluenza, rotavirus, adenovirus, hepatitis A, NonA NonB hepatitis, varicella, rabies, yellow fever, smallpox, Japanese encephalitis, flavivirus, dengue, toxoplasmosis, coccidiomycosis, schistosomiasis, and malaria immunogens.

288 (new). The method of claim 192 where said at least one immunogen being considered for an association comprises at least one of the following, BCG, measles, mumps, rubella, diphtheria, pertussis, Hemophilus influenza, tetanus, hepatitis B, polio, anthrax, plague, encephalitis, meningococcal, meningitis, pneumococcus, typhus, typhoid fever, streptococcus, staphylococcus, neisseria, lyme, cytomegalovirus (CMV), respiratory syncytial virus, Epstein Barr virus, herpes, influenza, parainfluenza, rotavirus, adenovirus, hepatitis A, NonA NonB hepatitis, varicella, rabies, yellow fever, smallpox, Japanese encephalitis, flavivirus, dengue, toxoplasmosis, coccidiomycosis, schistosomiasis, and malaria immunogens.

289 (new). The method of claim 193 where said at least one immunogen being considered for an association comprises at least one of the following, BCG, measles, mumps, rubella, diphtheria, pertussis, Hemophilus influenza, tetanus, hepatitis B, polio, anthrax, plague, encephalitis, meningococcal, meningitis, pneumococcus, typhus, typhoid fever, streptococcus, staphylococcus, neisseria, lyme, cytomegalovirus (CMV), respiratory syncytial virus, Epstein Barr virus, herpes, influenza, parainfluenza, rotavirus, adenovirus, hepatitis A, NonA NonB hepatitis, varicella, rabies, yellow fever, smallpox, Japanese encephalitis, flavivirus, dengue, toxoplasmosis, coccidiomycosis, schistosomiasis, and malaria immunogens.

290 (new). The method of claim 194 where said at least one immunogen being considered for an association comprises at least

one of the following, BCG, measles, mumps, rubella, diphtheria, pertussis, Hemophilus influenza, tetanus, hepatitis B, polio, anthrax, plague, encephalitis, meningococcal, meningitis, pneumococcus, typhus, typhoid fever, streptococcus, staphylococcus, neisseria, lyme, cytomegalovirus (CMV), respiratory syncytial virus, Epstein Barr virus, herpes, influenza, parainfluenza, rotavirus, adenovirus, hepatitis A, NonA NonB hepatitis, varicella, rabies, yellow fever, smallpox, Japanese encephalitis, flavivirus, dengue, toxoplasmosis, coccidiomycosis, schistosomiasis, and malaria immunogens.

291 (new). The method of claim 195 where said at least one immunogen being considered for an association comprises at least one of the following, BCG, measles, mumps, rubella, diphtheria, pertussis, Hemophilus influenza, tetanus, hepatitis B, polio, anthrax, plague, encephalitis, meningococcal, meningitis, pneumococcus, typhus, typhoid fever, streptococcus, staphylococcus, neisseria, lyme, cytomegalovirus (CMV), respiratory syncytial virus, Epstein Barr virus, herpes, influenza, parainfluenza, rotavirus, adenovirus, hepatitis A, NonA NonB hepatitis, varicella, rabies, yellow fever, smallpox, Japanese encephalitis, flavivirus, dengue, toxoplasmosis, coccidiomycosis, schistosomiasis, and malaria immunogens.

292 (new). The method of claim 196 where said at least one immunogen being considered for an association comprises at least one of the following, BCG, measles, mumps, rubella, diphtheria, pertussis, Hemophilus influenza, tetanus, hepatitis B, polio, anthrax, plague, encephalitis, meningococcal, meningitis, pneumococcus, typhus, typhoid fever, streptococcus, staphylococcus, neisseria, lyme, cytomegalovirus (CMV), respiratory syncytial virus, Epstein Barr virus, herpes, influenza, parainfluenza, rotavirus, adenovirus, hepatitis A, NonA NonB hepatitis, varicella, rabies, yellow fever, smallpox, Japanese encephalitis, flavivirus, dengue, toxoplasmosis, coccidiomycosis, schistosomiasis, and malaria immunogens.

293 (new). The method of claim 197 where said at least one

immunogen being considered for an association comprises at least one of the following, BCG, measles, mumps, rubella, diphtheria, pertussis, Hemophilus influenza, tetanus, hepatitis B, polio, anthrax, plague, encephalitis, meningococcal, meningitis, pneumococcus, typhus, typhoid fever, streptococcus, staphylococcus, neisseria, lyme, cytomegalovirus (CMV), respiratory syncytial virus, Epstein Barr virus, herpes, influenza, parainfluenza, rotavirus, adenovirus, hepatitis A, NonA NonB hepatitis, varicella, rabies, yellow fever, smallpox, Japanese encephalitis, flavivirus, dengue, toxoplasmosis, coccidiomycosis, schistosomiasis, and malaria immunogens.

294 (new). The method of claim 198 where said at least one immunogen being considered for an association comprises at least one of the following, BCG, measles, mumps, rubella, diphtheria, pertussis, Hemophilus influenza, tetanus, hepatitis B, polio, anthrax, plague, encephalitis, meningococcal, meningitis, pneumococcus, typhus, typhoid fever, streptococcus, staphylococcus, neisseria, lyme, cytomegalovirus (CMV), respiratory syncytial virus, Epstein Barr virus, herpes, influenza, parainfluenza, rotavirus, adenovirus, hepatitis A, NonA NonB hepatitis, varicella, rabies, yellow fever, smallpox, Japanese encephalitis, flavivirus, dengue, toxoplasmosis, coccidiomycosis, schistosomiasis, and malaria immunogens.

295 (new). The method of claim 199 where said at least one immunogen being considered for an association comprises at least one of the following, BCG, measles, mumps, rubella, diphtheria, pertussis, Hemophilus influenza, tetanus, hepatitis B, polio, anthrax, plague, encephalitis, meningococcal, meningitis, pneumococcus, typhus, typhoid fever, streptococcus, staphylococcus, neisseria, lyme, cytomegalovirus (CMV), respiratory syncytial virus, Epstein Barr virus, herpes, influenza, parainfluenza, rotavirus, adenovirus, hepatitis A, NonA NonB hepatitis, varicella, rabies, yellow fever, smallpox, Japanese encephalitis, flavivirus, dengue, toxoplasmosis, coccidiomycosis, schistosomiasis, and malaria immunogens.



296 (new). The method of claim 200 where said at least one immunogen being considered for an association comprises at least one of the following, BCG, measles, mumps, rubella, diphtheria, pertussis, Hemophilus influenza, tetanus, hepatitis B, polio, anthrax, plague, encephalitis, meningococcal, meningitis, pneumococcus, typhus, typhoid fever, streptococcus, staphylococcus, neisseria, lyme, cytomegalovirus (CMV), respiratory syncytial virus, Epstein Barr virus, herpes, influenza, parainfluenza, rotavirus, adenovirus, hepatitis A, NonA NonB hepatitis, varicella, rabies, yellow fever, smallpox, Japanese encephalitis, flavivirus, dengue, toxoplasmosis, coccidiomycosis, schistosomiasis, and malaria immunogens.

297 (new). The method of claim 156 wherein in at least one schedule of at least one immunogen being considered for an association is administered with a depot adjuvant.

298 (new). The method of claim 192 wherein in at least one schedule of at least one immunogen being considered for an association is administered with a depot adjuvant.

299 (new). The method of claim 193 wherein in at least one schedule of at least one immunogen being considered for an association is administered with a depot adjuvant.

300 (new). The method of claim 194 wherein in at least one schedule of at least one immunogen being considered for an association is administered with a depot adjuvant.

301 (new). The method of claim 195 wherein in at least one schedule of at least one immunogen being considered for an association is administered with a depot adjuvant.

302 (new). The method of claim 196 wherein in at least one schedule of at least one immunogen being considered for an association is administered with a depot adjuvant.

303 (new). The method of claim 197 wherein in at least one schedule of at least one immunogen being considered for an association is administered with a depot adjuvant.

304 (new). The method of claim 198 wherein in at least one schedule of at least one immunogen being considered for an

association is administered with a depot adjuvant.

305 (new). The method of claim 199 wherein in at least one schedule of at least one immunogen being considered for an association is administered with a depot adjuvant.

306 (new). The method of claim 200 wherein in at least one schedule of at least one immunogen being considered for an association is administered with a depot adjuvant.

307 (new). The method of claim 156 wherein data pertaining to at least one immunization schedule is from a clinical trial of a vaccine to test a vaccine for safety or efficacy.

308 (new). The method of claim 192 wherein data pertaining to at least one immunization schedule is from a clinical trial of a vaccine to test a vaccine for safety or efficacy.

309 (new). The method of claim 193 wherein data pertaining to at least one immunization schedule is from a clinical trial of a vaccine to test a vaccine for safety or efficacy.

310 (new). The method of claim 194 wherein data pertaining to at least one immunization schedule is from a clinical trial of a vaccine to test a vaccine for safety or efficacy.

311 (new). The method of claim 195 wherein data pertaining to at least one immunization schedule is from a clinical trial of a vaccine to test a vaccine for safety or efficacy.

312 (new). The method of claim 196 wherein data pertaining to at least one immunization schedule is from a clinical trial of a vaccine to test a vaccine for safety or efficacy.

313 (new). The method of claim 197 wherein data pertaining to at least one immunization schedule is from a clinical trial of a vaccine to test a vaccine for safety or efficacy.

314 (new). The method of claim 198 wherein data pertaining to at least one immunization schedule is from a clinical trial of a vaccine to test a vaccine for safety or efficacy.

315 (new). The method of claim 200 wherein data pertaining to at least one immunization schedule is from a clinical trial of a vaccine to test a vaccine for safety or efficacy.

316 (new). The method according to claim 156 where said

considering further comprises considering the severity of said disorder.

317 (new). The method according to claim 192 where said considering further comprises considering the severity of said disorder.

318 (new). The method according to claim 193 where said considering further comprises considering the severity of said disorder.

319 (new). The method according to claim 194 where said considering further comprises considering the severity of said disorder.

320 (new). The method according to claim 195 where said considering further comprises considering the severity of said disorder.

321 (new). The method according to claim 196 where said considering further comprises considering the severity of said disorder.

322 (new). The method according to claim 197 where said considering further comprises considering the severity of said disorder.

323 (new). The method according to claim 198 where said considering further comprises considering the severity of said disorder.

324 (new). The method according to claim 199 where said considering further comprises considering the severity of said disorder.

325 (new). The method according to claim 200 where said considering further comprises considering the severity of said disorder.

326 (new). The method of claim 156 wherein at least one said chronic immune mediated disorder comprises diabetes mellitus.

327 (new). The method of claim 192 wherein at least one said chronic immune mediated disorder comprises diabetes mellitus.

328 (new). The method of claim 193 wherein at least one said chronic immune mediated disorder comprises diabetes mellitus.

329 (new). The method of claim 194 wherein at least one said chronic immune mediated disorder comprises diabetes mellitus.

330 (new). The method of claim 195 wherein at least one said chronic immune mediated disorder comprises diabetes mellitus.

331 (new). The method of claim 196 wherein at least one said chronic immune mediated disorder comprises diabetes mellitus.

332 (new). The method of claim 197 wherein at least one said chronic immune mediated disorder comprises diabetes mellitus.

333 (new). The method of claim 198 wherein at least one said chronic immune mediated disorder comprises diabetes mellitus.

334 (new). The method of claim 199 wherein at least one said chronic immune mediated disorder comprises diabetes mellitus.

335 (new). The method of claim 156 where said disorder comprises at least one conventional organ specific autoimmune disorder and at least one of the following comprising at least one rheumatic disease/connective tissue disease, at least one autoimmune cytopenia, asthma.

336 (new). The method of claim 192 where said disorder comprises at least one conventional organ specific autoimmune disorder and at least one of the following comprising at least one rheumatic disease/connective tissue disease, at least one autoimmune cytopenia, asthma .

337 (new). The method of claim 193 where said disorder comprises at least one conventional organ specific autoimmune disorder and at least one of the following comprising at least one rheumatic disease/connective tissue disease, at least one

autoimmune cytopenia, asthma.

338 (new). The method of claim 194 where said disorder comprises at least one conventional organ specific autoimmune disorder and at least one of the following comprising at least one rheumatic disease/connective tissue disease, at least one autoimmune cytopenia, asthma.

339 (new). The method of claim 195 where said disorder comprises at least one conventional organ specific autoimmune disorder and at least one of the following comprising at least one rheumatic disease/connective tissue disease, at least one autoimmune cytopenia, asthma.

340 (new). The method of claim 196 where said disorder comprises at least one conventional organ specific autoimmune disorder and at least one of the following comprising at least one rheumatic disease/connective tissue disease, at least one autoimmune cytopenia, asthma.

341 (new). The method of claim 197 where said disorder comprises at least one conventional organ specific autoimmune disorder and at least one of the following comprising at least one rheumatic disease/connective tissue disease, at least one autoimmune cytopenia, asthma.

342 (new). The method of claim 198 where said disorder comprises at least one conventional organ specific autoimmune disorder and at least one of the following comprising at least one rheumatic disease/connective tissue disease, at least one autoimmune cytopenia, asthma.

343 (new). The method of claim 199 where said disorder comprises at least one conventional organ specific autoimmune disorder and at least one of the following comprising at least one rheumatic disease/connective tissue disease, at least one autoimmune cytopenia, asthma.

344 (new). The method of claim 200 where said disorder comprises at least one conventional organ specific autoimmune disorder and at least one of the following comprising at least one rheumatic disease/connective tissue disease, at least one

autoimmune cytopenia, asthma.

345 (new). The method of claim 156 wherein at least one said chronic immune mediated disorder comprises asthma.

346 (new). The method of claim 192 wherein at least one said chronic immune mediated disorder comprises asthma.

347 (new). The method of claim 193 wherein at least one said chronic immune mediated disorder comprises asthma.

348 (new). The method of claim 194 wherein at least one said chronic immune mediated disorder comprises asthma.

349 (new). The method of claim 195 wherein at least one said chronic immune mediated disorder comprises asthma.

350 (new). The method of claim 196 wherein at least one said chronic immune mediated disorder comprises asthma.

351 (new). The method of claim 197 wherein at least one said chronic immune mediated disorder comprises asthma.

352 (new). The method of claim 198 wherein at least one said chronic immune mediated disorder comprises asthma.

353 (new). The method of claim 199 wherein at least one said chronic immune mediated disorder comprises asthma.

354 (new). The method of claim 200 wherein at least one said chronic immune mediated disorder comprises asthma.

355 (new). The method of claim 193 wherein one immunization schedule provides at least one immunogen not provided by another screened schedule or fails to provide at least one immunogen provided by another screened schedule.

356 (new). The method of claim 195 wherein one immunization schedule provides at least one immunogen not provided by another screened schedule or fails to provide at least one immunogen provided by another screened schedule.

357 (new). The method of claim 198 wherein one immunization schedule provides at least one immunogen not provided by another screened schedule or fails to provide at least one immunogen provided by another screened schedule.

358 (new). The method of claim 200 wherein one immunization schedule provides at least one immunogen not provided by another

screened schedule or fails to provide at least one immunogen provided by another screened schedule.

359 (new). The method of any one of claims 156, 192-358 where the incidence, prevalence, frequency or risk was determined after a time span of at least one year after the administration of said one or more immunogens in the majority of humans.

360 (new). The method of claim 156 where the following conditions apply:

- \* at least one immunogen being considered for an association comprises at least one of the following, diphtheria, Hemophilus influenza, tetanus, hepatitis B, polio, anthrax, plague, encephalitis, meningococcal, meningitis, pneumococcus, typhus, typhoid fever, streptococcus, staphylococcus, neisseria, lyme, cytomegalovirus (CMV), respiratory syncytial virus, Epstein Barr virus, herpes, influenza, parainfluenza, rotavirus, adenovirus, hepatitis A, NonA NonB hepatitis, varicella, rabies, yellow fever, Japanese encephalitis, flavivirus, dengue, toxoplasmosis, coccidiomycosis, schistosomiasis, and malaria immunogens

- \* said human is immunized in III according to a schedule which is associated with a lower incidence, prevalence, frequency or risk compared to another schedule

- \* said at least one chronic immune mediated disorder is a hyperactive immune response

- \* the incidence, prevalence or frequency of at least one chronic immune-mediated disorder is considered

- \* data on at least two schedule is derived from groups of humans who had been randomized to receive the schedules

- \* one schedule provides at least one dose of at least one immunogen at a later or earlier time from birth than the corresponding dose of the same immunogen is provided by another schedule.

361 (new). The method of claim 360 where the following conditions apply:

- \* data pertaining to at least one immunization schedule is from a clinical trial of a vaccine to test a vaccine for safety

or efficacy

\* said immunization schedule prevents at least two infectious diseases.

362 (new). The method of claim 361 where the following conditions apply:

\* at least two immunization schedules differ by a difference in the number of doses of at least one immunogen administered to both schedules.

363 (new). The method of claim 360 where the following condition apply:

\* said at least one immunogen is administered by a route other than intravenously,  
subcutaneously, intradermally, or intramuscularly.

364 (new). The method of claim 362 where the following condition apply

\* said at least one immunogen is administered by a route other than intravenously,  
subcutaneously, intradermally, or intramuscularly.

365 (new). The method of claim 360 wherein one or more humans are excluded from receiving one or more immunogens if: i) said human have substantial immunologic protection against the infectious disease which said immunization schedule protects against, or ii) said human have an hyperactive immune response or iii) said human have a surrogate marker of an hyperactive immune response.

366 (new). The method of claim 364 wherein one or more humans are excluded from receiving one or more immunogens if: i) said human have substantial immunologic protection against the infectious disease which said immunization schedule protects against, or ii) said human have an hyperactive immune response or iii) said human have a surrogate marker of an hyperactive immune response.

367 (new). The method of claim 360 where the majority of humans receiving a schedule that does not include said one or more immunogens do not develop the infectious disease whose



protection is induced by said one or more immunogens.

368 (new). The method of claim 366 where the majority of humans receiving a schedule that does not include said one or more immunogens do not develop the infectious disease whose protection is induced by said one or more immunogens.

369 (new). The method of claim 360 where said chronic immune mediated disorder comprises asthma.

370 (new). The method of claim 361 where said chronic immune mediated disorder comprises asthma.

371 (new). The method of claim 365 where said chronic immune mediated disorder comprises asthma.

372 (new). The method of claim 366 where said chronic immune mediated disorder comprises asthma.

373 (new). The method of claim 368 where said chronic immune mediated disorder comprises asthma.

374 (new). The method according to claim 366 where said considering further comprises considering the severity of said disorder.

375 (new). The method according to claim 367 where said considering further comprises considering the severity of said disorder.

376 (new). The method according to claim 368 where said considering further comprises considering the severity of said disorder.

377 (new). The method according to claim 369 where said considering further comprises considering the severity of said disorder.

378 (new). The method according to claim 370 where said considering further comprises considering the severity of said disorder.

379 (new). The method according to claim 372 where said considering further comprises considering the severity of said disorder.

380 (new). The method according to claim 373 where said considering further comprises considering the severity of said

disorder.

381 (new). The method of claim 156 where the following conditions apply:

- \* at least one immunogen being considered for an association is a hepatitis B immunogen

- \* one schedule provides at least one dose of at least one immunogen at a later or earlier time from birth than the corresponding dose of the same immunogen is provided by another schedule

- \* at least one said chronic immune mediated disorder comprises diabetes mellitus

- \* at least one schedule of at least one immunogen being considered for an association is administered with a depot adjuvant

- \* said at least one immunogen being considered for an association is other than a live vaccine.

382 (new). The method of claim 381 where the following conditions apply:

- \* the first dose of said at least one immunogen in at least one said immunization schedules is given when the humans are less than 42 days old

- \* said considering further comprises consideration for at least one possible confounding variable selected from the group consisting of breast feeding, receiving antibiotics, the maternal age, family history of a chronic immune mediated disorder, maternal infections while the human was in utero, infections during the first 12 months of life, and size of the human at birth, gestational age of the human at birth, race, date of birth.

383 (new). The method of claim 382 where the following conditions apply:

- \* said at least one chronic immune mediated disorder is an autoimmune disease and is one other than diabetes

- \* the incidence, prevalence, frequency or risk was determined after a time span of at least one year after the

administration of said one or more immunogens in the majority of humans

\* said human is immunized in III according to a schedule which is associated with a lower incidence, prevalence, frequency or risk compared to another schedule.

384. The method of claim 156 where the following conditions apply:

\* said at least one immunogen being considered for an association comprises a measles, mumps, rubella vaccine

\* said considering further comprises consideration for at least one possible confounding variable selected from the group consisting of breast feeding, receiving antibiotics, the maternal age, family history of a chronic immune mediated disorder, maternal infections while the human was in utero, infections during the first 12 months of life, and size of the human at birth, gestational age of the human at birth, race, date of birth

\* at least one said chronic immune mediated disorder comprises diabetes mellitus.

385 (new). The method of claim 384 where the incidence, prevalence, frequency or risk was determined after a time span of at least one year after the administration of said one or more immunogens in the majority of humans.

386 (new). The method of claim 156 where the following conditions apply:

\* said at least one immunogen being considered for an association comprises at least one of the following, diphtheria, Hemophilus influenza, tetanus, hepatitis B, polio, anthrax, plague, encephalitis, meningococcal, meningitis, pneumococcus, typhus, typhoid fever, streptococcus, staphylococcus, neisseria, lyme, cytomegalovirus (CMV), respiratory syncytial virus, Epstein Barr virus, herpes, influenza, parainfluenza, rotavirus, adenovirus, hepatitis A, NonA NonB hepatitis, varicella, rabies, yellow fever, Japanese encephalitis, flavivirus, dengue, toxoplasmosis, coccidiomycosis, schistosomiasis, and malaria immunogens

- \* said at least one immunogen being considered for an association is first administered to at least one schedule starting after 41 days after birth but before 180 days after birth.

- \* said at least one immunogen being considered for an association is other than a live vaccine

- \* at least one said chronic immune mediated disorder comprises diabetes mellitus.

387 (new). The method of claim 386 where the following conditions apply:

- \* data on at least two immunization schedules is derived from groups of humans who had been randomized to receive the schedules

- \* the incidence, prevalence, frequency or risk was determined after a time span of at least one year after the administration of said one or more immunogens in the majority of humans

- \* one schedule provides at least one dose of at least one immunogen at a later or earlier time from birth than the corresponding dose of the same immunogen is provided by another schedule

- \* one schedule provides at least one immunogen not provided by another schedule or fails to provide at least one immunogen provided by another schedule

- \* two schedules differ by a difference in the number of doses of at least one immunogen administered in both schedules

- \* three or more immunization schedules are considered

- \* data pertaining to at least one immunization schedule is from a clinical trial of a vaccine to test a vaccine for safety or efficacy.

388 (new). The method of claim 387 where the following conditions apply:

- \* said at least one chronic immune mediated disorder comprises asthma

- \* said human is immunized in III according to a schedule

which is associated with a lower incidence, prevalence, frequency or risk compared to another schedule.

389 (new). The method of claim 386 where the following conditions apply:

- \* said considering further comprises consideration for at least one possible confounding variable selected from the group consisting of breast feeding, receiving antibiotics, the maternal age, family history of a chronic immune mediated disorder, maternal infections while the human was in utero, infections during the first 12 months of life, and size of the human at birth, gestational age of the human at birth, race, date of birth

- \* one schedule provides at least one dose of at least one immunogen at a later or earlier time from birth than the corresponding dose of the same immunogen is provided by another schedule

- \* one schedule provides at least one immunogen not provided by another schedule or fails to provide at least one immunogen provided by another schedule

- \* two schedules also differ by a difference in the number of doses of at least one immunogen administered in both schedules

- \* three or more schedules are considered.

390 (new). Method of claim 156 where the following conditions apply:

- \* said at least one immunogen being considered for an association is other than a live vaccine

- \* data on at least two immunization schedules is derived from groups of humans who had been randomized to receive the schedules

- \* at least one immunogen being considered for an association is first administered to at least one schedule starting after 41 days after birth but before 180 days after birth

- \* the incidence, prevalence, frequency or risk was determined after a time span of at least one year after the administration of said one or more immunogens in the majority of humans

- \* the incidence, prevalence or frequency of at least one chronic immune-mediated disorder is considered

- \* said at least one immunogen being considered for an association comprises at least one of the following, diphtheria, pertussis, Hemophilus influenza, tetanus, hepatitis B, polio, anthrax, plague, encephalitis, meningococcal, meningitis, pneumococcus, typhus, typhoid fever, streptococcus, staphylococcus, neisseria, lyme, cytomegalovirus (CMV), respiratory syncytial virus, Epstein Barr virus, herpes, influenza, parainfluenza, rotavirus, adenovirus, hepatitis A, NonA NonB hepatitis, varicella, rabies, yellow fever, Japanese encephalitis, flavivirus, dengue, toxoplasmosis, coccidiomycosis, schistosomiasis, and malaria immunogens

- \* at least one said chronic immune mediated disorder comprises diabetes mellitus

- \* data pertaining to at least one schedule is from a clinical trial of a vaccine to test a vaccine for safety or efficacy.

391 (new). The method of claim 390 wherein the following conditions apply:

- \* at least the majority of the mammals in a control group did not develop the infectious diseases which are prevented by said immunogen

- \* three or more schedules are considered

- \* at least two schedules differ by a difference in the number of doses of at least one immunogen administered to both schedules

- \* one schedule provides at least one immunogen not provided by another schedule or fails to provide at least one immunogen provided by another schedule

- \* said human is immunized in III according to a schedule which is associated with a lower incidence, prevalence, frequency or risk compared to another schedule.

392 (new). The method of claim 390 where said disorder comprises asthma and at least one autoimmune disease

393 (new). The method of claim 390 where said disorder comprises at least one conventional organ specific autoimmune disorder and at least one rheumatic disease/connective tissue disease and at least one autoimmune cytopenia.

394 (new). The method of claim 390 where said at least one said immunogen being considered for an association comprises an pneumococcal or meningococcal immunogen.

395 (new). Method of claim 156 where the following conditions apply:

- \* said at least one immunogen being considered for an association is other than a live vaccine

- \* said one or more immunogen being considered for an association comprises one other than a measles, mumps, rubella, BCG, or smallpox immunogen

- \* at least one immunogen being considered for an association is administered with a depot adjuvant

- \* at least one immunogen being considered for an association is first administered in at least one schedule starting after 41 days after birth but before 180 days after birth

- \* the incidence, prevalence, frequency or risk was determined after a time span of at least one year after the administration of said one or more immunogens in the majority of humans

- \* said considered further comprises consideration for at least one possible confounding variable selected from the group consisting of breast feeding, receiving antibiotics, the maternal age, family history of a chronic immune mediated disorder, maternal infections while the human was in utero, infections during the first 12 months of life, and size of the human at birth, gestational age of the human at birth, race, date of birth

- \* at least one said chronic immune mediated disorder comprises diabetes mellitus

- \* wherein in at least one schedule at least one immunogen being considered for an association is administered with a depot adjuvant.

396 (new). The method of claim 395 where said chronic immune mediated disorder comprises asthma.

397 (new). The method of claim 395 where at least one immunogen being considered for an association comprises a pertussis immunogen.

398 (new). The method of claim 156 wherein the following conditions apply:

- \* the majority of mammals receiving a schedule that does not include said one or more immunogens do not develop the infectious disease whose protection is induced by said one or more immunogens

- \* at least one schedule of at least one immunogen being considered for an association is administered with a depot adjuvant

- \* said chronic immune mediated disorder comprises diabetes mellitus

- \* at least one chronic immune mediated disorder other than diabetes is also considered

- \* at least two schedules also differ by a difference in the number of doses of at least one immunogen administered to both schedules

- \* said one or more immunogen being considered for an association comprises one other than a measles, mumps, rubella, BCG, smallpox or pertussis immunogen .

- \* said at least one immunogen being considered for an association is other than a live vaccine.

399 (new). The method of claim 398 where at least one said immunogen is an anthrax immunogen.

400 (new). The method of claim 398 where the incidence, prevalence, frequency or risk was determined after a time span of at least one year after the administration of said one or more immunogens in the majority of humans.

401 (new). The method of claim 399 where the incidence, prevalence, frequency or risk was determined after a time span of at least one year after the administration of said one or more



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immunogens in the majority of humans.

402 (new). The method of claim 399 where said human is immunized in III according to a schedule which is associated with a lower incidence, prevalence, frequency or risk compared to another schedule.

403 (new). The method according to claim 194 where the association is statistically significant.